

REMARKS

Claims 1-9, and 13 remain in this application. In the instant correspondence, claim 9 has been cancelled without prejudice to prosecuting the same (or a similar) claim in a subsequently filed patent application.

Claims 1-9, and 13 were rejected. The Examiner made the following rejections:

- I. The Examiner rejected claim 9, under 35 U.S.C. § 102(b), as allegedly being anticipated by Caruso (U.S. Patent 6,043,244). In addition, the Examiner rejects claim 9, under 35 U.S.C. § 102(b), as allegedly being anticipated by Plachetka (U.S. Patent 5,872,145).
- II. The Examiner rejects Claims 1, 2, 4-9 and 13, under 35 U.S.C. § 103(a), as allegedly being unpatentable over Caruso (U.S. Patent 6,043,244) or Plachetka (U.S. Patent 5,872,145). In addition, the Examiner rejects claim 3, under 35 U.S.C. § 103(a), as allegedly being unpatentable over Caruso or Plachetka in combination with Azia *et al.* (U.S. Patent 4,758,423) or Plachetka *et al.* (U.S. Patent 6,495,535).

Claims 1-8, and 13 remain in this application. Claim 9 has been cancelled without prejudice to prosecuting the same (or similar) claim in a subsequently filed patent application.

I. The Pending Rejection Under 35 U.S.C. 102(b) Is Moot

In order to advance business interests and without acquiescing to the Examiner's arguments, while expressly reserving the right to prosecute the original claim as filed (or a claim similar thereto), the Applicant has cancelled claim 9. Given that claim 9 was the only claim rejected, under 35 U.S.C. 102(b), in the Office Action mailed November 04, 2003; the Applicant respectfully submits this rejection is moot and should, therefore, be withdrawn.

II. The Claims Are Not Obvious Under 35 U.S.C. § 103(a)

Claims 1, 2, 4-9 and 13 stand rejected as allegedly unpatentable over Caruso *or* Plachetka. With regard to both references, the Examiner stated:

"At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to formulate a sublingual composition that contains DHE and a pH-adjusting agent. Elimination of an ingredient as well as its function does not impart patentability to a well-known formulation in the absence of said ingredient.

One of ordinary skill in the art would have been motivated to do this to provide a method of treating migraines that is effective and achieves the effect in a short amount of time to bring quick and direct relief to the host.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made."¹

Once again the Applicant reminds the Examiner that *both* Caruso and Plachetka are completely silent on the incorporation of a pH modulating agent which can alter the microenvironment in the area of administration (e.g. in one example the sublingual mucosa) such that the base form of DHE is favored over the far less absorbable mesylate salt.

In the application as filed the Applicant presents a detailed analysis detailing, in selected embodiments, the advantages of modulating pH while administering DHE. Specifically, the Applicant notes:

"A sublingual formulation of DHE in the base form of the drug would permit the use of lower doses of DHE since a greater portion of the medication would be absorbed directly into the blood stream thereby allowing a direct route to the afflicted target area."²

and,

"Although the present invention is not limited to any particular mechanism, it is believed that the adjustment of the pH of the environment of the sublingual area will convert the administered DHE to the readily absorbable DHE base."³

¹ Office Action mailed 11/04/03, pages 4 & 5.

² Application as filed, page 3, ll. 27-30.

³ Application as filed, page 4, ll. 21-23.

As already noted by the Applicant, in the Preliminary Amendment filed August 8, 2003, bald speculation by the Examiner is insufficient authority to challenge the patentability of the pending claims. That is to say, in order to *properly* rebut the specific advantages (*vis-a-vis* the modulation of pH in selected embodiments of the present invention) as taught in the specification, the Examiner needs provide evidence which challenges the advantages *already made of record* by the Applicant.

The requirement that the Examiner make a showing of a suggestion, teaching or motivation is "an essential evidentiary component of an obviousness holding." *C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1352 (Fed. Cir. 1998). There are three sources for this evidentiary component: the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996). The suggestion most often comes from the teachings of the pertinent references. *In re Rouffet*, 149 F.3d 1350, 1359 (Fed. Cir. 1998). Nonetheless, regardless of the source of the requisite evidence, the Examiner's showing "must be clear and particular, and broad conclusory statements . . . standing alone, are not 'evidence'." *In re Dembiczak*, 175 F.3d 994, 1000 (Fed. Cir. 1999).

It is the Examiner's burden to present "evidence" and this showing must be "clear and particular." Importantly, since an Examiner is NOT one skilled in the art (under the law), the Examiner's opinion on what one skilled in the art might believe is of no moment. *In re Rijckaert*, 9 F.3d 1531, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993) ("[T]he examiner's assumptions do not constitute the disclosure of the prior art.").

While the Examiner presents a string of citations to both Caruso and Plachetka, nothing in any of these citations⁴ teach or suggest the incorporation of "a pH adjusting agent" into methods for the treatment of migraine (as currently recited in the claimed embodiments in the pending application). That is to say, the Examiner only provides opinion and conclusory statements in labeling (as obvious) a limitation incorporated into each of the pending claims of the instant application. Given the Examiner's failure to: i) consider and

⁴ The Examiner also cites to U.S. patent 4,758,423 (Azria *et al.*) and U.S. patent 6,495,535 (Plachetka *et al.*) in rejecting the pending claims under 35 U.S.C. 103. However, since both the '423 or '535 patents are silent on the modulation of pH during the administration of DHE (in methods for the treatment of migraine); the Applicant respectfully submits these patents are of no moment with regard to the alleged obviousness of claimed embodiments of the present invention.

give weight to *all* claim limitations⁵ and ii) provide *evidence* rebutting the Applicant's fact-based showing of the non-obviousness of the pending claims; the Applicant respectfully submits the pending rejections, under 35 U.S.C. 103, be withdrawn.

CONCLUSION

The Applicant believes the amendments and arguments, set forth in the instant correspondence, traverse the Examiner's rejections and, therefore, request that all grounds for rejection be withdrawn for the reasons set out above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicant encourages the Examiner to call the undersigned collect at 617.984.0616.

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⁵ See, *In re Saether*, 181 USPQ 37, 39 (CCPA 1974).